



Office for Human Research Protections
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April 23, 2007

Jeffrey M. Cheek, Ph.D.
Associate Vice Provost for Research
Compliance and Operations
Office of Research
University of Washington
G80 Gerberding Hall
Seattle, WA 98195-1202

RE: Human Subjects Protections Under Federalwide Assurance FWA-6878

<u>Research Project:</u>	Casa Pia Study of Dental Amalgams in Children
<u>Principal Investigator:</u>	Dr. Timothy A. DeRouen
<u>IRB Number:</u>	95-0401-A/C 10
<u>HHS Project Number:</u>	5U01DE011984

Dear Dr. Cheek:

The Office for Human Research Protections (OHRP) has reviewed the University of Washington's (UW) March 8, 2007 and April 5, 2007 reports that were submitted in response to OHRP's December 13, 2006 letter regarding the above-referenced research.

In its December 13, 2006 letter, OHRP found that the informed consent document for the above-referenced research failed to adequately describe the reasonably foreseeable risks of amalgams and composite materials used in the dental procedures, as required by Department of Health and Human Services regulations at 45 CFR 46.116(a)(2).

Corrective Action: OHRP notes that UW has developed a new policy and guidance for institutional review board (IRB) members and investigators regarding the inclusion of the risks associated with standard of care procedures in the informed consent document. OHRP also notes that UW plans to educate IRB members and investigators about this new policy. In addition, UW will revise its informed consent templates to include a reference to this policy.

OHRP finds that the above corrective action adequately addresses the determination made in OHRP's December 13, 2006 letter. As a result of this determination, there should be no need of further involvement of OHRP in this matter.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Patrick J. McNeilly, Ph.D.
Compliance Oversight Coordinator
Division of Compliance Oversight

cc: Dr. Karen Moe, Acting Director, Humans Subjects Division, UW
Dr. Zane Brown, Chair Human Subjects Committee A, UW
Dr. Alan Wilenski, Chair Human Subjects Committee B, UW
Dr. Patricia Kuszler, Chair Human Subjects Committee C, UW
Dr. Rebekah Rein, Chair Human Subjects Committee D, UW
Dr. Carl Rimmele, Chair Human Subjects Committee G, UW
Dr. Donald Sherrard, Chair Human Subjects Committee V, UW
Dr. Deborah McCutchen, Chair Human Subjects Committee J, UW
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